## REMARKS

Applicant expresses appreciation to the Examiner for consideration of the subject patent application. In this application, claims 1-17 are pending, claims 18-33 have been withdrawn. This communication is in response to the Office Action mailed October 11, 2007, in which the following actions were taken:

(1) Claims 1-17 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,103,112 to Sutton et al. (hereinafter "Sutton"); and

(2) Claims 5, 6, 9, and 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sutton in view of U.S. Patent No. 6,423,120 to Nickerson et al. (hereinafter "Nickerson").

Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

**Claim Rejections - 35 U.S.C. § 102**

Claims 1-17 (including independent claims 1, 9, and 10) were rejected under 35 U.S.C. § 102(b) as being anticipated by Sutton. Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. § 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied,* 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989).

In order to most succinctly explain why the claims presented herein are allowable, Applicant will direct the following remarks primarily to the independent claims 1, 9, and 10 with the understanding that once an independent claim is allowable, all claims depending therefrom are allowable.

The present claims set forth methods for treating chromatographic fluid, in which fluid is passed through a short length of tubing and rapidly heated or cooled. The embodiment set forth in present independent claim 1 requires that this rapid heating or cooling of fluid be accomplished before the same fluid enters the chromatography column. Independent claim 9 provides for extremely rapid heating or cooling in a range encompassing rates of several hundred watts. Independent claim 10 sets forth a particular protocol in which the temperature of the fluid is measured between the heating or cooling means and the column.

Sutton discloses a chromatographic apparatus in which heating or cooling is provided by either moving air from a fan or a conduction source in metal-to-metal contact with a heat conducting block in which the chromatography column and inlet tubing are embedded. See e.g. Figures 4-7 and 9. In one embodiment in Sutton, the inlet tubing is coiled in a receptacle in the heat conducting block, so that only the surface of the tubing facing outward is in direct contact with the block. In another embodiment disclosed in Sutton, inlet tubing is enclosed in a labyrinth within the block.

Applicants submit that Sutton does not teach all of the elements required by the present independent claims 1, 9, or 10. Claim 1 requires that the claimed rapid heating or cooling of fluid be done before the fluid enters the column. In all of the apparatus disclosed by Sutton, not only the inlet tubing, but also the chromatography column are enclosed within the heating/cooling source (air) or in heat conducting relationship with the source. See col 13, lines 43-46. As such, the mobile phase in Sutton is heated generally throughout the tube and column. Sutton does not teach a particular rapid heating or cooling rates of several hundred watts as set forth in Applicants' claim 9. Finally, the arrangement disclosed in Sutton as described above — where the tubing and column are both enclosed within a heat conducting block—does not provide for temperature sensing of the fluid by a sensor connected to the tube closer to the column than the heating/cooling means as required by claim 10. In Sutton, the conducting block conducts heat to/from the whole apparatus, and thus, the rapid heating or cooling is not

configured to occur specifically through the tubing as presently claimed. Rather, it teaches general heating throughout the block. It is noted that claim 1 is not intended to specifically exclude heating or cooling in general at other locations, but rather, requires rapid heating or cooling of the fluid through the tubing before the fluid enters the column, which is neither taught nor suggested by Sutton. The use of such a heating block does not allow particularly for rapid heating or cooling. In addition, the temperature sensor of Sutton is embedded in the block and so measures the temperature of the block, not the fluid in the tube as required by the present claims.

As Sutton fails to teach each and every element of the present independent claims 1, 9, and 10, that reference does not anticipate those claims. The same is true of claims 2-8 and 11-17, which each include the limitations of claims 1 or 10. Therefore, Applicant respectfully requests that this rejection be withdrawn.

**Claim Rejections - 35 U.S.C. § 103**

Before discussing the obviousness rejections herein, it is thought proper to briefly state what is required to sustain such a rejection. The issue under § 103 is whether the PTO has stated a case of *prima facie* obviousness. The framework for this analysis is provided in the factual inquiries set forth in *Graham v John Deere Co.*, 383 U.S. 1 (1966), which form the background for all determinations of obviousness. See also *KSR Int'l Co. v Teleflex Inc.*, 127 S. Ct. 1727 (2007).

According to the MPEP § 2142, the Examiner has the burden and must establish a case of *prima facie* obviousness by showing the prior art reference, or references combined, teach or suggest all the claim limitations in the instant application. Further, the Examiner has to establish some motivation, suggestion, or reason to combine and/or modify the references, where the motivation, suggestion, or reason must arise from the references themselves, or the knowledge generally available to one of ordinary skill in the art. The Applicant respectfully asserts the Examiner has not satisfied the requirement for establishing a case of *prima facie* obviousness in any of the rejections as discussed in turn below.

*Sutton alone*

In the alternative to the above rejection under § 102, the Examiner has also rejected claims 1-17 under 35 U.S.C. § 103 as being unpatentable over Sutton. The failure of Sutton to teach each and every element of the present claims is discussed above and Applicants hereby reassert these arguments here. In short, Sutton does not teach rapidly heating or cooling of fluid before it enters the column as required by claim 1, nor does it teach high heating/cooling rates of claim 9 or temperature measurement situated between the heating/cooling means and the column as set forth in claim 10. Applicants submit that these limitations are neither taught nor suggested by Sutton so as to present a *prima facie* case of obviousness. The Examiner has stated that any differences between Applicants' claims and the disclosure of Sutton reside in obvious optimization of the steps in Sutton. Applicants respectfully disagree. In particular, there is no teaching of the arrangement required in both claims 1 and 10, i.e. one that allows rapid heating/cooling to be performed on a portion of the tubing that is upstream from the column (and, in the case of claim 10, upstream from the temperature measurement). The embodiments described in Sutton clearly show the column as enclosed within the heat conducting block, making them incompatible with the claimed method. In addition, Sutton provides no teaching of the heating/cooling rates required by claim 9. Furthermore, the conducting block of Sutton is large relative to the separation apparatus, so that the column, a sizable length of tubing, a heating/cooling element, and other components may be enclosed within. Due to its size, the block changes temperature more slowly because there is more mass to heat or cool. Such a block will be less responsive and less able to heat or cool at such high rates. One skilled in the art would not look to the arrangement of Sutton to achieve the responsiveness needed for such rapid temperature changes.

In light of the above, Applicants submit that, because Sutton does not teach or suggest each and every element of the present independent claims, these claims and those dependent from them are patentable over Sutton.

*Sutton in view of Nickerson*

The Examiner has rejected claims 5, 6, 9, 15 under 35 U.S.C. § 103(a) as being unpatentable over Sutton in view of Nickerson. Specifically, Nickerson is cited to provide a

teaching of the rates of temperature modification required by Applicants' claims, which the Examiner has acknowledged is lacking in Sutton. Applicants submit that Nickerson does not provide this teaching, and does not present a *prima facie* case of obviousness in combination with Sutton.

The heater discussed in Nickerson and referred to by the Examiner involves a heater block and heater cartridge assembly typically weighing approximately 4 oz. (113 g). Col 5, lines 35-45. This is a high-mass heater that, as Nickerson points out, requires a higher energy heater to achieve "reasonable heat-up rates." Therefore in Nickerson, 60 watts refers to the power of the heater, not to the actual rate of heating that the fluid undergoes due to heat transfer. Nickerson does not indicate exactly what heating rate is achieved with the setup described, beyond characterizing it as "reasonable." It is unlikely that the apparatus described in Nickerson would exhibit the rates recited in the present claims, which are possible with low-mass heating elements (e.g. 10 – 200 mg; see Applicants' specification at pg 6, lines 3-7). One skilled in the art would expect that such performance is even less likely when used with the apparatus of Sutton. Based on a combination of its structure as exemplified in Figures 6, 7, and 9 and the materials used (aluminum or copper), the heating/cooling assembly of Sutton should have an even higher mass than that described in Nickerson, and therefore even lower rates of temperature modification. As such, Applicants submit that one skilled in the art would not combine the teachings of Nickerson and Sutton, and that these references do not yield the present invention even if combined. Applicants therefore request that this rejection be withdrawn.

## CONCLUSION

In light of the above, Applicant respectfully submits that pending claims 1-17 are now in condition for allowance. Therefore, Applicant requests that the rejections and objections be withdrawn, and that the claims be allowed and passed to issue. If any impediment to the allowance of these claims remains after entry of this Amendment, the Examiner is encouraged to call Gary Oakeson at (801) 566-6633 so that such matters may be resolved as expeditiously as possible.

The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 20-0100.

DATED this 11th day of January, 2008.

Respectfully submitted,

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